

CHAPTER 03: FOODBORNE MICROBIOLOGICAL HAZARDS

SUBJECT: IMPORT FOOD OPERATIONS		IMPLEMENTATION DATE: 10/20/2021
DATA REPORTING		
PRODUCT CODES	PRODUCT/ASSIGNMENT CODES (PAC)	
USE APPROPRIATE PRODUCT CODES	REPORT PROGRAM ACTIVITIES UNDER THE FOLLOWING PAC CODES: Foreign Supplier Verification Programs (FSVP) Inspections <hr/> 03878 (FOREIGN SUPPLIER VERIFICATION PROGRAMS HUMAN FOOD INSPECTIONS) 03878D (FOREIGN SUPPLIER VERIFICATION PROGRAMS DIETARY SUPPLEMENT INSPECTIONS) 03878P (FOREIGN SUPPLIER VERIFICATION PROGRAMS PRODUCE INSPECTIONS) 71878 (FOREIGN SUPPLIER VERIFICATION PROGRAMS ANIMAL FOOD INSPECTIONS)	

FIELD REPORTING REQUIREMENTS:

Investigators must use eNSpect to complete the Establishment Inspection Report (EIR) for an FSVP inspection (OP12) or for an investigation (OP13). See [Investigations Operations Manual](#) (IOM) subchapter 5.11 - *Reporting* and subchapter 8.1.9 - *General Investigation Reporting* for additional reporting instructions. An exception for creating an EIR or a related document (e.g., Form FDA 483a) or an investigation memorandum in eNSpect must be endorsed by the investigator’s supervisor. IOM subchapter 5.11.2.1 – *Reporting Verified Corrective Actions* directs Office of Regulatory Affairs (ORA) field staff to document corrective actions taken during an inspection in the Corrective Action Reporting (CAR) system within eNSpect.

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Change History

Item	Change	Date
Initial Issuance		10/20/2021

PART I – BACKGROUND

This Import Food Operations compliance program is based on FDA’s mission to protect and promote public health, in line with the [FDA Strategy for the Safety of Imported Food](#). This compliance program details legal and regulatory requirements for imported food as well as administrative, inspection, and enforcement activities relating to human and animal food imported to the United States (U.S.).

FDA’s strategy for the safety of imported food is to ensure that the food was produced using processes and procedures that provide at least the same level of public health protection as food produced in the U.S. To operationalize the FDA's Food Safety , FDA must apply risk-based approaches to mitigate food safety risk.

Chapter VIII of the Federal Food, Drug, and Cosmetic Act (FD&C Act) gives FDA authority and responsibility to regulate imported products. Section 801 of the FD&C Act gives FDA authority to refuse admission to products that do not meet certain U.S. requirements and includes additional requirements specific to imported products, importers, and the import process.

Section 301 of the FDA Food Safety Modernization Act (FSMA) added section 805, Foreign Supplier Verification Programs, to the FD&C Act. Section 805 enhanced our authority to ensure the safety of imported food. In November 2015, FDA published the [Foreign Supplier Verification Programs for Food Importers \(FSVP\)](#) regulation (21 CFR part 1, subpart L) .

1. Summary of Requirements

Section 1.500 of the FSVP regulation defines importer to mean:

- The U.S. owner or consignee of an article of food that is being offered for import into United States.
- If there is no U.S. owner or consignee of an article of food at the time of U.S. entry, the importer is the U.S. agent or representative of the foreign owner or consignee at the time of entry, as confirmed in a signed statement of consent to serve as the importer under the FSVP regulation.

This compliance program hereinafter refers to “importer” as defined in section 1.500 of the FSVP regulation as “importer” or “FSVPI.”

Section 1.502(a) of the FSVP regulation requires the FSVPI to develop, maintain, and follow an FSVP that provides adequate assurances that the FSVPI’s foreign supplier is in compliance with processes and procedures that provide at least the same level of public health protection as those required under:

- Section 418 of the FD&C Act (regarding hazard analysis and risk-based preventive controls) and the implementing regulations, or

- Section 419 of the FD&C Act (regarding standards for produce safety) and the implementing regulations.

Section 1.502(a) of the FSVP regulation also requires the FSVPI to ensure that the foreign supplier is producing the food in compliance with sections 402 (regarding adulteration) and section 403(w) (if applicable) (regarding misbranding with respect to labeling for the presence of major food allergens for human food) of the FD&C Act.

Section 1.509 of the FSVP regulation requires the FSVPI to ensure that, for each entry line of food they offer for importation into the U.S., they provide FDA electronically their name, electronic mail address, and unique facility identifier (UFI) recognized as acceptable when filing entry with U.S. Customs and Border Protection (CBP). The importer's DUNS number is the UFI that is recognized as acceptable by FDA. See [Guidance to Industry: Recognition of Acceptable Unique Facility Identifier \(UFI\) for the Foreign Supplier Verification Programs Regulation](#) for more information on the FSVPI's use of their DUNS number as their UFI.

The FSVP regulation establishes requirements for FSVPIs of food, definitions, exemptions from the FSVP regulation, and the consequences for failure to comply with the FSVP regulation. FDA has designated certain sections of the FSVP regulation as standard requirements and modified requirements.

A. FSVP Definitions, Exemptions, Consequences

FSVP definitions, exemptions, and consequences are:

- Section [1.500](#) What definitions apply to this subpart?
- Section [1.501](#) To what foods do the requirements in this subpart apply?
- Section [1.514](#) What are some consequences of failing to comply with the requirements of this part?

B. FSVP Standard Requirements

The FSVP standard requirements are:

- Section [1.502](#) What foreign supplier verification program (FSVP) must I have?
- Section [1.503](#) Who must develop my FSVP and perform FSVP activities?
- Section [1.504](#) What hazard analysis must I conduct?
- Section [1.505](#) What evaluation for foreign supplier approval and verification must I conduct?
- Section [1.506](#) What foreign supplier verification and related activities must I conduct?
- Section [1.508](#) What corrective actions must I take under my FSVP?
- Section [1.509](#) How must the importer be identified at entry?
- Section [1.510](#) How must I maintain records of my FSVP?

C. FSVP Modified Requirements

The FSVP modified requirements are:

- Section [1.507](#) What requirements apply when I import a food that cannot be consumed without the hazards being controlled or for which the hazards are controlled after importation?
- Section [1.511](#) What FSVP must I have if I am importing a food subject to certain requirements in the dietary supplement current good manufacturing practice regulation?
- Section [1.512](#) What FSVP may I have if I am a very small importer or I am importing certain food from certain small foreign suppliers?
- Section [1.513](#) What FSVP may I have if I am importing certain food from a country with an officially recognized or equivalent food safety system?

2. FSVP Exemptions

Section 1.501 FSVP regulation applies to all food imported or offered for import into the U.S. and to the FSVPIs of such food, except as follows:

- Certain juice, fish, and fishery products that are imported from a foreign supplier that is required to comply with, and is in compliance with, the requirements in 21 CFR part 120 or part 123 (1.501(b)(1))
- Certain juice or seafood raw materials or other ingredients that are imported and used in manufacturing or processing of juice subject to 21 CFR part 120 or fish and fishery products subject to 21 CFR part 123, provided that the importer is in compliance with the requirements in part 120 or part 123 with respect to the juice or fish or fishery product they manufacture or process from the imported raw materials or other ingredients (1.501(b)(2))
- Food imported for research or evaluation (1.501(c))
- Food imported for personal consumption (1.501(d))
- Alcoholic beverages, alcoholic beverage raw materials and ingredients used by the FSVPI to manufacture/process an alcoholic beverage, and certain non-alcohol foods (1.501(e))
- Food that is transhipped through the United States or imported for processing and export to other countries (1.501(f))
- U.S. food returned (1.501(g))
- Certain meat, poultry, and egg products that at the time of importation are subject to the requirements of the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*) or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*) (1.501(h))

3. Enforcement Discretion

FSVP guidance documents relating to enforcement discretion may be found at the FDA.gov web page [FSMA Rules & Guidance for Industry](#).

PART II – IMPLEMENTATION

1. Objectives

- Conduct FSVP inspections for importers of food subject to the *Foreign Supplier Verification Programs for Food Importers* regulation.
- Document FSVP inspections and observations.
- Perform appropriate regulatory actions to prevent importation of food by importers not in compliance with the FSVP regulation or food that appears to be in violation of the FD&C Act.

While the focus in the initial issuance of this compliance program is on FSVP inspections, CFSAN plans to expand this program to include general import operations at a later date.

2. Program Management Instructions

ORA Divisions are responsible for ensuring that investigators verify, correct, and enter changes to the Official Establishment Inventory (OEI) (including Profile data) on the firm's maintenance screens in eNSpect during each inspection and investigation. Investigators should consult with their supervisor and OEI Coordinator to ensure data is accurately updated.

A. Inspection Priorities

Center for Food Safety and Applied Nutrition (CFSAN), Center for Veterinary Medicine (CVM), and ORA/Office of Enforcement and Import Operations (OEIO) are responsible for developing prioritization criteria for selecting FSVPIs for FSVP inspections. ORA/OEIO will select FSVPIs for surveillance and compliance follow up inspections from the FSVPI inventory. For-cause FSVP inspections may also be requested by the Import Field Divisions, Division of Import Operations (DIO), CFSAN, and CVM. See [FSVP Implementation Work Instructions](#) for additional information on the procedure for assigning inspections in eNSpect.

When selecting an FSVPI for an FSVP inspection, Divisions should prioritize the FSVPI inventory according to the following criteria:

- **Priority #1: Compliance History**

FSVPIs with history of noncompliance with the FSVP regulation or who import from a foreign supplier with a history of noncompliance should be the first priority for FSVP inspection. History of noncompliance includes class 1 recalls, laboratory class 3 microbiological findings, official action indicated (OAI) inspection classifications, and foodborne illness outbreaks. History of noncompliance would also include situations where a country of origin as a whole is associated with a trend of noncompliance for a specific food or industry.

- **Priority #2: High-Risk Foods**

Importers of high-risk foods (i.e., foods that may pose a health risk) are the second priority. See Part II.2.B. below for further information on foods designated as high-risk.

- **Priority #3: Other Supply Chain Factors**

After considering the compliance history and high-risk foods, the Division should prioritize FSVP inspections based on other relevant factors, including:

- number of different foods imported by the FSVPI,
- number of foreign suppliers from which an FSVPI imports foods, and
- volume and value of the lines of food imported by the FSVPI.

These factors will help maximize our surveillance coverage for the highest number of foreign food supply chains.

B. Selection of High-Risk Food Coverage During FSVP Inspection

The investigator should cover FSVPs for high-risk foods during an FSVP inspection of an FSVPI, if available (see section II.2.A. priority #2). High-risk food that should be prioritized for FSVP inspection coverage include:

- Ready-to-eat food (RTE food) for which pathogen cross-contamination is a significant hazard because the food is exposed to the environment prior to packaging and does not undergo further processing or otherwise contain a control measure to significantly minimize pathogens. Ready-to-eat food (RTE food) is defined in [21 CFR 117.3](#) to mean any food that is normally eaten in its raw state or any other food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards.
- Raw agricultural commodities (RACs) that are “covered produce” under 21 CFR 112.3 (e.g., leafy greens, cucumbers, tomatoes, peppers, cantaloupes, honeydew, papayas).
- Human food for which undeclared major food allergens or a major food allergen present in the food due to cross-contact are significant hazards.
- Foods that are intended for use by special populations, such as children, the elderly, and persons who are immunocompromised.
- Food for which a process control (e.g., cooking pasteurization, refrigeration) is required to ensure control of a hazard requiring control.
- Finished dietary supplements.
- Pet food, pet treats, and chews.

C. Planning Instructions

The ORA [Import Program Workplan](#) identifies the number of FSVP inspections that Divisions should complete each fiscal year. FSVP inspections must be conducted only by investigators who have successfully completed the following:

- Food Safety Preventive Controls Alliance (FSPCA) Preventive Controls for Human Food course,
- FSPCA Foreign Supplier Verification Programs course, and
- FDA’s Office of Training Education and Development (OTED) IM220 Foreign Supplier Verification Programs Regulator Course.

Additionally:

- Investigators conducting FSVP inspections of produce importers must have successfully completed the Produce Safety Alliance for Growers Training course.
- Investigators conducting FSVP inspections of animal food importers must have successfully completed the FSPCA Preventive Controls for Animal Food course.
- Investigators conducting FSVP inspections of importers of dietary supplements that are subject to the requirements of section 1.511 of the FSVP regulation must be knowledgeable of the [Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements](#) (dietary supplements CGMP) regulation (21 CFR part 111).
- Refer to the [FSVP Implementation Work Instructions](#) for additional information on how to meet training requirements.

D. Resources and Reporting

All FSVP operations conducted under this compliance program will be created in eNSpect Basic Work Request (BWR). FDA staff should refer to the [Basic Work Request \(BWR\) User Guide](#) for any questions on the use of BWR in eNSpect to create operations. OEIO will generate a new eNSpect Assignment ID each fiscal year. FDA staff must not create an ad-hoc FSVP operation for this compliance program without discussing with the DIO FSMA Team and the program coordinator identified in part VI of this compliance program. Divisions should coordinate resources to ensure that inspections conducted under this compliance program meet inspection obligations under other compliance programs that also apply. See Table 1 below for additional resources and reporting information.

Table 1 – Resources and Reporting			
Activity	Work Types	Planning PAC Code	Reporting PAC Code
Foreign Supplier Verification	Op 12 Inspection	03878	03878 (FOREIGN SUPPLIER VERIFICATION PROGRAMS)
	Op 13 Investigation	71878	

Programs Inspections			HUMAN FOOD INSPECTIONS) 71878 (FOREIGN SUPPLIER VERIFICATION PROGRAMS ANIMAL FOOD INSPECTIONS) 03878D (FOREIGN SUPPLIER VERIFICATION PROGRAMS DIETARY SUPPLEMENT INSPECTIONS) 03878P (FOREIGN SUPPLIER VERIFICATION PROGRAMS PRODUCE INSPECTIONS)
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E. Program Interactions

Programs that interact with this compliance program include the following:

- (1) **Preventive Controls and Sanitary Human Food Operations ([CP 7303.040](#)) or Comprehensive Animal Foods Inspection ([CP 7371.000](#))**

An FSVPI that is a manufacturer/processor subject to the [Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food](#) regulation (preventive controls for human food) (21 CFR part 117) or the [Current Good Manufacturing Practice, Hazard Analysis and Risk-Based Preventive Controls for Food for Animals](#) (preventive controls for animal food) regulation (21 CFR part 507) that imports a raw material or other ingredient they use in the food they manufacture/process may be subject to an inspection to determine compliance with the preventive controls for human food regulation or preventive controls for animal food regulation and may also be subject to the FSVP regulation. An importer that is not a receiving facility for a food they import must comply with the FSVP requirements for that food.

An FSVPI that is also a facility solely engaged in the storage of unexposed packaged food requiring time/temperature control for food safety and that is subject to inspection to determine compliance with modified requirements in section [117.206](#) for human food or section [507.51](#) for animal food may be subject to an FSVP inspection. Similarly, an FSVPI that is a facility solely engaged in the storage of unexposed packaged food not requiring time/temperature control for food safety (i.e., ambient warehouse) and is subject only to the CGMP requirements found in subpart B of 117 or 507 may also be subject to an FSVP inspection.

(2) Dietary Supplements – Foreign and Domestic Inspections, Sampling, and Imports (CP 7321.008)

An FSVPI that imports a dietary supplement or dietary supplement component for further manufacturing, processing, or packaging as a dietary supplement by the FSVPI or their customer and they or their customer are subject to inspection to determine compliance with certain requirements in the [Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements](#) (dietary supplements CGMP) regulation may also be subject to an FSVP inspection.

F. Food Facility Registration

An FSVPI may also be a facility that is required to register under section 415 of the FD&C Act “because it manufactures, processes, packs, or holds food for consumption in the United States.” If Division staff determine that an FSVPI is also a facility that is required to register and the facility is operating with no registration, a suspended registration, an invalid registration, or a cancelled registration, or that the registration in the Food Facility Registration Module (FFRM) is not accurate, the Division staff should send an email to CFSANFoodFacilityRegistration@fda.hhs.gov in accordance with IOM subchapter 5.4.1.5.2, *Food Facility Registration Resources*. When food facility registration is discussed during an inspection of a facility that is required to register, the investigator should document the discussion in the EIR.

G. Interactions with Federal Agencies, State and Local Counterparts, and Foreign Authorities

(1) Federal Agencies

Interaction with other Federal agencies is not expected for FSVP inspections.

(2) State and Local Counterparts

Currently, FDA is not assigning FSVP inspections to State and Local counterparts.

(3) Foreign Authorities

To determine whether a food covered during an FSVP inspection is covered by a Systems Recognition Arrangement (SRA) with a country with an officially recognized or equivalent human food safety system to that of the U.S., and thus the FSVPI may be eligible for modified requirements in section [1.513](#) of the FSVP regulation, see FDA’s website: [Systems Recognition \(Food\)](#).

The modified FSVP requirements in section [1.513](#) of the FSVP regulation apply only to foods that are not intended for further manufacturing/processing and are within the scope of the applicable SRA.

H. When to Contact Other Offices within FDA

Import Divisions should share their FSVP inspection assignments with the appropriate OHAFO Divisions at the beginning of the fiscal year and exchange quarterly accomplishment updates thereafter. Import Divisions should coordinate with OHAFO Divisions to ensure that they are not inspecting a facility or farm more than once per year, except when a for-cause inspection is necessary. Additionally, Divisions should determine if there are any pending administrative or regulatory actions or ongoing investigations relating to the food, foreign supplier, or FSVPI before conducting an FSVP inspection.

- For FSVPIs for which there are overlapping inspection responsibilities for OEIO and OHAFO the appropriate field Division will coordinate inspection activities to ensure we provide consistent and timely inspections that fulfill ORA's commitment to industry relating to inspection coverage and also to ensure that qualified staff are conducting inspections.
- CFSAN, CVM, or DIO may issue a for-cause FSVP inspection assignment for one or more FSVPIs of a food that is subject to a recall, implicated in a foodborne outbreak, from a foreign supplier with an OAI inspection, or for which data indicates an emerging food safety concern.

For questions pertaining to the content of this compliance program or its implementation, please contact the appropriate individuals identified in [part VI](#) of this compliance program.

The Regulator Technical Assistance Network (rTAN) is a resource primarily for investigators to request assistance during inspections. It is not intended to replace the current enforcement communication mechanism between field inspection staff, supervisors, and compliance officers. The rTAN is an information assistance system designed to connect field inspection staff with Subject Matter Experts (SMEs) to get answers and clarification on interpretation of a FSMA regulation and for specific food-related questions, as needed.

(1) Human Food rTAN

Investigators should send all human food rTAN inquiries relating to FSVP inspections conducted under this compliance program to FSVPrTAN@fda.hhs.gov. As necessary, FSVP rTAN members will reach out to SMEs on the rTAN list for FSMA rule policy interpretation or for clarification on commodity-specific hazards (e.g., produce, ready-to-eat foods, foods refrigerated for safety, dietary supplements).

Investigators may reach out to additional SMEs on the [rTAN list](#) as appropriate based on the food being covered and the nature of the question. However, ALL applicable SMEs must be included in all communications to ensure consistent information is provided and to prevent duplication of effort. The investigator may contact rTAN directly via e-mail prior to or during an inspection. If the investigator is asking the question during an

inspection and needs a response as soon as possible, they should include “Inspection in Progress” in the email’s subject line.

(2) Animal Food rTAN

Investigators should email CVMAnimalFoodPrograms@fda.hhs.gov or call 301-796-0001 with questions before, during, or after an inspection of an FSVPI that imports animal food. Investigators should include “rTAN” or “Regulator TAN” in the subject line of their email. A CVM rTAN Coordinator will forward the question to the appropriate CVM SMEs, summarize the final answer, and respond to the investigator in the manner the question was received (i.e., email or telephone).

PART III – INSPECTIONAL

1. Operations

A. Inspections

Investigators will conduct FSVP inspections under this compliance program to evaluate the FSVPI's compliance with the FSVP regulation. As appropriate to enhance the FSVPI's understanding of the FSVP regulation, the investigator should reference or provide the FSVPI with a copy of relevant FSVP resources, such as:

- [*Final Rule on Foreign Supplier Verification Programs*](#)
- [*Key Requirements: Final Rule on Foreign Supplier Verification Program*](#)
- [*Foreign Supplier Verification Programs for Importers of Food for Humans and Animals \(FSVP\) Regulation Records Requirements*](#) to help the FSVPI determine the required records for the sections in the FSVP regulation that apply to their food they import.
- [*Recognition of Acceptable Unique Facility Identifier \(UFI\) for the Foreign Supplier Verification Programs Regulation*](#) to help the FSVPI understand the requirement in section 1.509 to provide their DUNS number as part of their importer identification for each line entry of food.

The investigator will discuss with the importer significant observations listed on Form FDA 483a, FSVP Observations, and also discuss with the importer other observations that are not significant. The investigator will document the discussion in the EIR (see IOM 5.2.3).

The investigator will encourage the FSVPI to take corrective actions for deviations observed during the inspection. The investigator will document in the EIR all corrective actions taken by the FSVPI during the inspection and any corrective actions the importer indicated they plan to take, including the importer's timeframe for correction. In addition, the investigator will document in the corrective action reporting system (CAR) within eNSpect any corrective actions taken by the FSVPI during the inspection and any corrective actions received as a result of the inspection.

Investigators should refer to the [FSVP Implementation Work Instructions](#) for additional instructions covering how to conduct an FSVP inspection.

(1) FSVP Inspection of FSVPI of Covered Produce

An investigator conducting an FSVP inspection of a produce FSVPI must have successfully completed the Produce Safety Alliance for Growers Training course and must be knowledgeable of the [Standards for the Growing, Harvesting, Packing, and Holding of](#)

[Produce for Human Consumption](#) (21 CFR part 112). See Part II.2.C. for investigator training requirements. To determine if the produce covered during an FSVP inspection is “covered produce” investigators should:

- Review the [“covered produce” list 21 CFR 112.1](#) and
- Review the [“not covered produce” list 21 CFR 112.2](#).

(2) FSVP Inspection of FSVPI of Dietary Supplements

Investigators conducting FSVP inspections of importers of dietary supplements that are subject to the requirements of section 1.511 of the FSVP regulation must be knowledgeable of the [Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements](#) (dietary supplements CGMP) regulation (21 CFR part 111). See Part II.2.C. for further investigator training requirements.

B. Investigations

FSVP domestic Investigations (OP13) may be performed under this compliance program. See IOM subchapter 8.1.9, *General Investigation Reporting*, for guidance covering how to conduct and report an investigation.

C. Sample Collections

Samples will not be collected as part of an FSVP inspection.

D. Other

FDA has not made a finding that compliance with section 1.507 of the FSVP regulation would overcome the appearance of a violation under section 801(a) of the FD&C Act (e.g., the food offered for importation into the U.S. is subject to refusal and listed on an import alert; FDA sample is Lab Class 3).

2. Reporting

The EIR and Inspection Protocol (IP) for an FSVP inspection must be completed in eNSpect as instructed in IOM subchapter 5.11. FSVP Investigational Memorandums must be prepared according to IOM subchapter 8.1.9. Corrective actions taken during an FSVP inspection must be reported in the Corrective Action Reporting system (CAR). Use eNSpect to report corrective actions observed during the inspection and those received after the inspection but before the inspection report is finalized in eNSpect. Use CMS to report and assess any corrective actions

received after the EIR has been finalized in eNSpect. Investigators should complete the CAR web-based training before initially using CAR to enter corrective actions.

FDA staff should contact the ORA Apps Desk via the [Employee Resource and Information Center \(ERIC\)](#) for questions or issues pertaining to the functionality of eNSpect, the FSVP IP, or CAR.

PART IV – ANALYTICAL**1. Analyzing Laboratories**

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2. Analyses to be Conducted

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3. Methodology

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4. Reporting

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PART V - REGULATORY/ADMINISTRATIVE STRATEGY

1. Findings

The FSVP regulatory/administrative strategy is intended to obtain industry compliance with the FSVP regulation. Divisions will encourage the FSVPI to voluntarily correct observations identified during an FSVP inspection. However, an FSVPI who does not take appropriate corrective actions to comply with the FSVP regulation will be subject to appropriate enforcement action.

A. FSVP Inspection Observations

ORA/OEIO staff should refer to [FSVP Implementation Work Instructions](#) for information on determining the regulatory significance of inspection observations listed on Form FDA 483a.

The most significant FSVP inspection observations are those that may impact the FSVPI's development or implementation of an FSVP or that prevent or interfere with FDA's review of the FSVPI's FSVP. These may include:

- The FSVPI did not conduct a hazard analysis or review of another entity's hazard analysis, including when the lack of a hazard analysis impacted development or implementation of their FSVP (e.g., the FSVPI did not conduct appropriate foreign supplier verification activities for a food having a SAHCODHA hazard) (21 CFR 1.504(a) and (d))
- The FSVPI did not conduct and document an evaluation of their foreign supplier for approval or to determine appropriate verification activities (21 CFR 1.505(a)(2) and 1.511(c)(4), (5))
- The FSVPI did not conduct and document foreign supplier verification activities (21 CFR 1.506(e)(1))
- The FSVPI did not document an FSVP activity required for compliance with an FSVP modified requirement (e.g., for a food for which the hazards are controlled after importation, the FSVPI did not provide a disclosure statement as required in 1.507(a)(2)(i), (3)(i), or (4)(i))
- The importer did not provide FSVP records electronically, or through another means to deliver the records promptly to FDA, after FDA requested the records in writing. (21 CFR 1.510(b)(3), 1.511(a), (b), 1.511(c)(1), 21 CFR 1.512(b)(5)(ii)(C), or 21 CFR 1.513(a)(1))

FSVP inspection observations that are significant, but may not impact or prevent the FSVPI's implementation of FSVP to provide adequate assurance that the foreign supplier is producing the food in compliance with applicable sections of the Act, may include:

- The importer did not document their approval of the foreign supplier. (21 CFR 1.505(b), 1.511(c)(1))

- The importer did not establish written procedures for ensuring they import foods only from approved foreign suppliers (21 CFR 1.506(a)) or for ensuring that appropriate foreign supplier verification activities were conducted with respect to an imported food. (21 CFR 1.506(b))
- The importer did not establish written procedures for ensuring that appropriate foreign supplier verification activities were conducted with respect to an imported food. (21 CFR 1.506(b))
- The importer did not document changes made to their FSVP after determining that their foreign supplier was not in compliance with applicable FDA food safety standards. (21 CFR 1.508(b), 1.511(c)(1))

Other FSVP inspection observations not included above may be considered less significant but may be discussed with the FSVPI during the inspection or included in combination with more significant observations in a recommendation for an enforcement action.

B. Corrective Actions

Voluntary corrective action is often the most effective and expedient means by which to obtain compliance. Divisions should take steps to obtain voluntary corrective action prior to initiating regulatory action. When voluntary corrective action is not forthcoming, the ORA/OEIO Divisions should pursue routine regulatory procedures to address significant observations. Refer to [*FMD-86 Establishment Inspection Report Conclusions and Decisions*](#) for further information.

The Division may consider informal communication (e.g., email, telephone calls) with an FSVPI when there are questions relating to corrections submitted in their response to the Form FDA 483a for which clarification may impact the Division's decision to pursue regulatory actions or to determine if a follow-up inspection is necessary.

2. Charges

An FSVPI that is not in compliance with the requirements of the FSVP regulation (21 CFR part 1, subpart L) is not in compliance with section 805 of the FD&C Act. FDA may refuse admission into the United States of a food offered for import if it appears that the FSVPI is not in compliance with the FSVP requirements with respect to that food (section 801(a)(3) of the FD&C Act; 21 CFR 1.514(a)). The charge for refusing entry of a food for which the importer is not in compliance with the requirements of section 805 of the FD&C Act is:

The article is subject to refusal of admission pursuant to section 801(a)(3) of the FD&C Act in that it appears that the importer (as defined in section 805 of the FD&C Act) is in violation of section 805.

In addition, the importing or offering for importation of a food into the United States without the FSVPI having an FSVP in accordance with section 805 of the FD&C Act, including the requirements of the FSVP regulation, is a prohibited act under section 301(zz) of the FD&C Act (21 U.S.C. 331(zz)); 21 CFR 1.514(b).

Under section 302 of the FD&C Act (21 U.S.C. 332), the United States can bring a civil action in Federal court to enjoin a person who commits a prohibited act. Under section 303 of the FD&C Act (21 U.S.C. 333), the United States can bring a criminal action in Federal court to prosecute a person who is responsible for the commission of a prohibited act. Under section 306 of the FD&C Act (21 U.S.C. 335a), FDA can seek debarment of any person who has been convicted of a felony relating to importation of food into the United States. In addition, false representations to the U.S. government, including falsely identifying a U.S. agent or representative, may result in criminal prosecution of those involved.

3. Actions

All FSVP compliance cases will be routed to the Import Division Compliance Branch responsible for the geographical location where the inspection was conducted based on the FSVPI's place of business. A recommendation for an enforcement action based on FSVP violations (i.e., warning letter or listing on Import Alert 99-41 recommendation) must be routed in CMS to CFSAN OC DE Food Adulteration and Assessment Branch (CFSAN OC DE FAAB) or CVM Division of Surveillance and Compliance (CVM OSC DC), as appropriate. See [FSVP Implementation Work Instructions](#) for additional information. Direct reference authority for enforcement authority relating to FSVP (i.e., FSVP warning letter or listing on Import Alert 99-41) has not been provided to the Divisions.

A. FSVP Warning Letter

Divisions should consider recommending to CFSAN or CVM issuance of a warning letter to an FSVPI who did not take appropriate corrective actions for significant FSVP violations. Divisions should consider the regulatory significance and repetition of the violations, as well as other factors that may impact the effectiveness of obtaining compliance such as voluntary corrective actions. Divisions should recommend issuance of a warning letter for violations of regulatory significance. Significant violations are violations that may lead to listing the FSVPI, food, and foreign supplier combination on Import Alert 99-41 if they are not promptly and adequately corrected. Divisions should consider conducting a regulatory meeting with the FSVPI prior to recommending issuance of a warning letter when the Division believes a discussion of the violations and their significance may result in voluntary corrective action.

B. FSVP Import Alert

[Import Alert 99-41](#) "Detention Without Physical Examination of Human and Animal Foods Imported from Foreign Suppliers by Importers Who Are Not in Compliance with the

Requirements of the Foreign Supplier Verification Programs (FSVP) Regulation" provides for detention without physical examination of an article of human or animal food offered for import by an FSVPI that is not in compliance with the FSVP regulation.

(1) Addition of FSVPI, Food, and Foreign Supplier (Combination) on Import Alert 99-41

If an FSVPI does not take appropriate corrective actions to significant FSVP violations after receiving a warning letter, or does not respond to a warning letter, the Division should consider a recommendation to place the FSVPI on the Red List of Import Alert 99-41 for each specific food and specific foreign supplier combination or for all foods, as appropriate, for which the FSVPI is not in compliance with the FSVP regulation. Divisions may consider recommending the FSVPI for all imported foods and foreign suppliers subject to FSVP when the evidence in the EIR supports such.

An FSVPI that is not listed on the Red List of FSVP Import Alert 99-41 may continue to import the same food and other foods from a listed foreign supplier, provided the food or foreign supplier are not subject to an import alert for the appearance of adulteration or misbranding.

(2) Removal of FSVPI, Food, and Foreign Supplier (Combination) from Import Alert 99-41

The FSVPI should follow the instructions stated in Import Alert 99-41 to submit information supporting their request for removal. The request should be sent to the Division that issued the regulatory letter notifying the FSVPI of their FSVP violations and placement on Import Alert 99-41. If the Division determines that the FSVPI provided sufficient evidence of appropriate corrective actions, the Division will submit a recommendation in CMS to OEIO/DIO to remove the FSVPI for each specific food and foreign supplier combination, or for all foods, as appropriate, from the Red List. OEIO/DIO will consult with CFSAN OC DE or CVM OSC DC to determine whether to remove the FSVPI from the Red List.

The Division may review a petition for removal from Import Alert 99-41 that addresses removal of all or a large number of foods, which should include evidence of compliance with the FSVP regulation for all of the foods, by reviewing a representative number of FSVPs. The Division may consider reviewing a representative number of FSVPs as described in the Regulatory Procedures Manual (RPM), Chapter 9-8-18, REMOVAL OF IMPORTERS. When selecting FSVPs for review, the Division should consider reviewing:

- FSVPs for food from different foreign suppliers to assure that the FSVPI conducted appropriate supplier verification activities for multiple foreign suppliers (e.g., audits of each foreign supplier of a food associated with a SAHCODHA hazard).
- An FSVP that adequately represents a type of food (i.e., an FSVP for one of the same type of food for which the same hazard analysis applies).
- An FSVP for one of several foods for which the same verification activities apply.

Alternatively, the Division may review specific FSVP records submitted to determine, in general, that the importer demonstrates an understanding of the FSVP requirements and is in compliance with FSVP. For example, the Division may review:

- A hazard analysis for one or more foods associated with a SAHCODHA hazard (See 21 CFR 1.504)
- Documentation of foreign supplier verification activities conducted by the importer or another entity (e.g., documentation of onsite audits, including a copy of the audits; sampling and testing results, and food safety records reviewed by the FSVPI) (See 21 CFR 1.506)
- Written procedures for foreign supplier approval based on the evaluation conducted under 1.505 (See 21 CFR 1.506(a))
- Written procedures for ensuring that appropriate foreign supplier verification activities are conducted (See 21 CFR 1.506(b))

After the Division has reviewed sufficient FSVPs or FSVP records to have assurance that the FSVPI is meeting the requirements of FSVP for future entries of all foods, or for specific foods from a foreign supplier, and it appears the conditions that gave rise to the addition of such to Import Alert 99-41 have been overcome, the Division may recommend removal of the FSVPI, food, and foreign supplier combination, or all foods from the Red List of Import Alert 99-41, as appropriate.

Divisions should encourage FSVPIs to request removal from Import Alert 99-41 prior to attempting to import a specific food from a specific foreign supplier, or all foods, as appropriate. If an entry is subject to refusal and the importer is listed on the Red List of Import Alert 99-41 for the food and foreign supplier combination, any testimony received in response to a Notice of FDA Action should be evaluated to consider compliance with the FSVP regulation for all entries of the food being imported by that importer. If a Division other than the Division that inspected the FSVPI receives testimony from an importer of record that appears to be a petition for removal from Import Alert 99-41 for an FSVPI for specific food from a specific foreign supplier, the receiving Division will refer the testimony to the Division responsible for the FSVP inspection. If the Division receives a request to extend the time period for responding to the Notice of FDA Action, particularly when the requester is the FSVPI, in responding to the extension request the Division should consider that the FSVPI received a warning letter advising them of their

FSVP violations, and the FSVPI was provided adequate opportunity to correct the violations prior to being placed on the Red List of Import Alert 99-41.

Removal of an FSVPI, food, and foreign supplier combination from Import Alert 99-41 does not preclude the FDA from taking future enforcement action, based on subsequent determination that the FSVPI is in violation of the FSVP regulation.

4. Regulatory Follow-Up

Divisions will determine whether the importer provided adequate documentation of compliance with FSVP for the FSVPs reviewed during the previous inspection. During the follow-up inspection, if the FSVPI did not provide adequate documentation that they corrected significant observations relating to FSVPs reviewed during the previous inspection, the investigator may review the same FSVPs, as appropriate to verify corrective actions taken by the FSVPI or select one or more different FSVPs for review.

5. Foreign Owner or Consignee Follow-Up

If the results of an FSVP Investigation (OP13) indicate there was no U.S. owner or consignee for the food at the time of entry and the foreign owner or consignee did not designate a U.S. agent or representative to serve as the FSVPI, as agreed in writing, the Division's Investigations Branch should submit their investigation package to their Import Division's Compliance Branch (CB). The CB should prepare a foreign owner or consignee letter (see [FSVP Implementation Work Instructions](#)) and submit in CMS using the "FSVP Informational Letter" work type, to CFSAN OC DE or CVM OSC DC. CFSAN or CVM will coordinate review of the letter with DIO and Office of the Chief Counsel (OCC), and, as appropriate, will send the cleared letter to the foreign owner or consignee. The DIO FSMA Team will subsequently monitor food entries from the foreign supplier to determine whether additional follow-up is needed to verify that the FSVPI is accurately identified at entry, as required in section 1.509 of the FSVP regulation.

6. Other

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PART VI - REFERENCES, ATTACHMENTS, AND PROGRAM CONTACTS

1. References

- A. [Investigations Operations Manual](#)
- B. [Regulatory Procedures Manual](#)
- C. [21 CFR Part 1 Subpart L Foreign Supplier Verification Programs for Food Importers](#)

- D. [Draft Guidance for Industry: Describing a Hazard That Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing FSMA](#)
- E. [FMD-86 Establishment Inspection Report Conclusions and Decisions](#)
- F. [Final Rule, Federal Register Notice September 17, 2015](#)
- G. [Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Foods](#)
- H. [Form FDA 483a, FSVP Observations](#)
- I. [Form FDA 482d, Request for FSVP Records](#)
- J. [Key Requirements: Final Rule on Foreign Supplier Verification Programs](#)
- K. [Final Rule on Foreign Supplier Verification Programs](#)
- L. [Guidance to Industry: Recognition of Acceptable Unique Facility Identifier \(UFI\) for the Foreign Supplier Verification Program](#)
- M. [Food Safety Plan Builder](#)
- N. [Reportable Food Registry \(RFR\) At A Glance fact sheet](#)
- O. [SOP 51](#)
- P. [Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Food for Animals](#)
- Q. [FSVP Implementation Work Instructions](#)

2. Attachments

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3. Program Contacts

A. CFSAN

Purpose	Name	Organization	Contact
General Program Contact	Mark Farrell	CFSAN/OC/DFPG/PAMB	Mark.farrell@fda.hhs.gov
Enforcement questions	Aleta Flores	CFSAN/OC/DE	Aleta.flores@fda.hhs.gov
Compliance Policy Questions	Yinqing Ma	CFSAN/OC/CPS	Yinqing.Ma@fda.hhs.gov

B. CVM

Purpose	Name	Organization	Contact
CVM Policy	Isaac Carney	CVM/OSC/DC	Isaac.carney@fda.hhs.gov
CVM Import/FSVP Questions	Sean Cheney	CVM/OSC/DC	Sean.cheney@fda.hhs.gov

C. ORA

Purpose	Name	Organization	Contact
General Imports/FSVP Questions	ORA OEIO DIO Inquiries	ORA/OEIO/DIO	FDAImportsInquiry@fda.hhs.gov
Dietary Supplement/CVM Questions	Lourdes Andujar	ORA/OHAFO/DD HAFO	Lourdes.andujar@fda.hhs.gov
General Food Questions	Linda Stewart	ORA/OHAFO/DD HAFO	Linda.stewart@fda.hhs.gov

PART VII - CENTER RESPONSIBILITIES

CFSAN's Office of Compliance and CVM's Office of Surveillance and Compliance are the lead offices for evaluating this compliance program. CFSAN and CVM will provide subject matter expertise for evaluating this compliance program and provide information relating to program priorities, relevant evaluation questions, and recommended program changes. CFSAN and CVM will evaluate this compliance program on a periodic basis. The evaluation will include a statement of the compliance program objectives, general and specific program evaluation questions, a list of recommendations for process improvement, and highlights of data patterns and trends for better targeting and resource allocation. CFSAN's Office of Compliance will make the evaluations and FSMA Tracker reports available annually or as frequently as needed to track accomplishments.